MAR 2 4 2014

# 510(k) Summary

Date: March 1, 2013

Manufacturer:
Encore Medical, L.P.
Trade Name: DJO Surgical
9800 Metric Blvd
Austin, TX 78758

Contact Person:
William Garzon
Regulatory Affairs Specialist
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| Product | Classification | Product Code |
|---|---|---|
| RSP Modular Glenoid Baseplate | Class II | KWS |

| Product Code | Regulation and Classification Name |
|---|---|
| KWS | Shoulder joint metal/polymer semi-constrained prosthesis per 21 CFR 888.3660 |

**Description**:
The purpose of this application is to include a new modularity option for the existing RSP baseplate. The RSP Modular Glenoid Baseplate is a multiple piece construct as opposed to a single piece construct as the predicate Reverse Shoulder Prosthesis Baseplate (K041066).

The RSP Modular Glenoid Baseplate is fabricated from wrought/forged Ti-6A1-4V that conforms to ASTM F136. The bottom surface of the baseplate is porous coated with commercially pure titanium (ASTM F67 grade 2) beads. This is the same coating previously cleared under K974294. The baseplate is Hydroxyapatite coated that conforms to ASTM F1185. The distal surface of the glenoid baseplate is porous coated with an incorporated 6.5mm cancellous screw and is intended to be used with four peripheral screws (3.5mm non-locking and/or 5mm locking and non-locking) for additional fixation.

The RSP Modular Glenoid Baseplate female taper and male taper of the adapter have geometry identical to those used in the predicate Turon Shoulder (K080402).

There are no changes to sterilization, packaging, indications or intended use.

**Indications for Use:**
Indicated for use in patients with a grossly rotator cuff deficient shoulder joint with severe arthropathy or a previously failed joint replacement with a grossly rotator cuff deficient shoulder joint. The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary to use the device. The glenoid baseplate is intended for cementless application with the addition of screws for fixation. The humeral stem is intended for cemented use only.

**Predicate Device:**

- Reverse Shoulder Prosthesis – K041066
- Turon Shoulder – K080402

**Comparable Features to Predicate Device(s):**

Features comparable to predicate devices include the same indications, sterilization, packaging and intended use.

**Non-Clinical Testing:**
Mechanical fatigue testing, Dynamic testing. Results of non-clinical testing demonstrate that the device is as safe, as effective, and performs as well as the predicate device.

**Clinical Testing:** None provided

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 24, 2014

Encore Medical, L.P.
Mr. William Garzon
Regulatory Affairs Specialist
9800 Metric Boulevard
Austin, Texas 78758

Re: K130550
Trade/Device Name: RSP Modular Glenoid Baseplate
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained prosthesis
Regulatory Class: Class II
Product Code: KWS
Dated: February 13, 2014
Received: February 18, 2014

Dear Mr. Garzon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K130550

Device Name: RSP Modular Glenoid Baseplate

Indications for Use:

Indicated for use in patients with a grossly rotator cuff deficient shoulder joint with severe arthropathy or a previously failed joint replacement with a grossly rotator cuff deficient shoulder joint. The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary to use the device. The glenoid baseplate is intended for cementless application with the addition of screws for fixation. The humeral stem is intended for cemented use only.

| Prescription Use ___X___ (Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____ (21 CFR 801 Subpart C) |
|---|---|---|

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices